

REMARKS

New Claim

New claim 27 is added. Claim 27 uses the “consisting of” language, but is identical to claim 10 in every other respect.

The Rejection under 35 USC § 103

Claims 10-19 were rejected as allegedly unpatentable over Mansanobu, JP 10226650, in view of Takada, JP 3-255037.

The Office Action relied on a computer-translated version of Mansanobu. Because the computer-translated version of the reference does not correctly reflect the teachings relied on in the Office Action applicants attach a verified translation of said reference.

Masanobu teaches that the glycyrrhizin or salt thereof is solubilized in a solubilizing agent and that said solubilized product is coated with an enteric coating film. See claim 1, and page 6, lines 2-7. Mansanobu on page 7, lines 1-6, teaches that

delivery of a drug and an absorption promoter to the large intestine in solid state was not effective to improve the absorption sufficiently.

The present invention has solved this problem by solubilizing the solid drug and absorption promoter in a solubilizing agent.

Production examples 1-6 of Mansanobu each yield a clear solution, and not a shaped core.

Production example 7-1 teaches that the solution was “processed into a soft capsule” (emphasis added). This language refers to the solution being filled into a soft capsule, i.e., the solution not being a shaped core. Nowhere does the reference teach or suggest that a shaped core is formed which contains glycyrrhizin, which is a feature of every claim of the present application.

With respect to the new claim, the reference also fails to teach or suggest an embodiment “consisting of” the elements recited in the claim. Each oral formulation of Mansanobu contains at least one soft capsule containing the solution. Such formulation is excluded by the claim language used in new claim 27.

Takada also does not offer any teaching or suggestion for the preparation of a shaped core, and no allegation is made to that effect. Takada teaches an ethylcellulose capsule that contains a “drug solution or drug suspension,” which is disintegrated by the inner pressure of the large intestine. See column 3, lines 1-14. Neither reference teaches or suggests a shaped core. Thus, the claims are not obvious for at least this reason.

The Commissioner is hereby authorized to charge any fees associated with this response or credit any overpayment to Deposit Account No. 13-3402.

Respectfully submitted,


Ceaba Henter, Reg. No. 50,908
John A. Sopp, Reg. No. 33,103
Attorneys for Applicants
MILLEN, WHITE, ZELANO & BRANIGAN, P.C.
Arlington Courthouse Plaza 1
2200 Clarendon Boulevard, Suite 1400
Arlington, VA 22201
Direct Dial: 703-812-5331
Facsimile: 703-243-6410
Email: henter@mwzb.com

Filed: November 7, 2003

AJZ/CH(pdr):K:\AKA\269\Reply Nov 2003.doc